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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/939,093	08/24/2001	Graham Nigel Maw	PC10347AGLK	2991

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EXAMINER	
ROYDS, LESLIE A	
ART UNIT	PAPER NUMBER
1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/939,093	MAW ET AL.	
	Examiner	Art Unit	
	Leslie A. Royds	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 February 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) *1-6 and 14-31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/4/02 and 4/2/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-31 are presented for examination.

Applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d) from United Kingdom Patent Application No. 0021487.4 filed September 1, 2000 and Applicant's claim for priority under 35 U.S.C. 119(e) from provisional application number 60/238,206 filed October 5, 2000, is acknowledged. Applicant's Preliminary Amendment filed August 24, 2001 has been received and entered into the application. Accordingly, the present specification at page 1, immediately following the title, has been amended. Applicant's Information Disclosure Statements filed February 4, 2002 and April 2, 2002 have been received and entered into the application. As reflected by the attached, completed copy of Form PTO-FB-A820 (3 pages total), the Examiner has considered the cited references. Applicant's "Response to Restriction/Election Requirement" filed February 8, 2005 has been received and entered into the application.

Election/Restriction Requirement

Applicant's election **with traverse** of Group II (claims 7-13), drawn to a method of treatment comprising administering to a subject an agent capable of modulating an IK_{Ca} channel activity in the sexual genitalia of a subject, in the reply filed February 8, 2005 is acknowledged. The traversal is on the grounds that the Examiner has not shown that a serious burden exists in examining all the claims together, particularly with respect to the claims of Groups I and II. Applicant has also traversed on the grounds that the present restriction requirement would require the filing of numerous applications directed to individual aspects of the invention, of which the cost for prosecution and maintenance of all such applications would be unreasonable.

Applicant's traverse has been carefully considered, but is not found persuasive because the Examiner maintains that each of the inventions of Groups I through VIII are patentably distinct and independent inventions based upon the fact that each invention contains distinctly different subject matter from any one or more of the other inventions and that each invention is individually capable of supporting a separate patent. Performance of a complete and comprehensive search of any one of the inventions would not necessarily result in a complete search of the prior art for any other invention based on the evidence of distinctly different subject matter, mode of operation, function or effect for the reasons made of record at pages 3-10 of the previous Office Action dated December 21, 2004. Furthermore, execution of a search encompassing all of Applicant's multiple inventions would not only constitute an undue burden on the Examiner, but consideration of the findings of such a search in accordance with the requirements of the law under 35 U.S.C. §§ 101, 102, 103 and 112 would also be unduly burdensome. Thus, restriction between the inventions of Groups I through VIII as indicated in the previous Office Action is proper and firmly grounded in the teachings of the MPEP at §800.

The Examiner further maintains that the composition of Group I (claims 1-6) is a patentably distinct and independent invention from the method of Group II (claims 7-13). Although Applicant has traversed on the grounds that the Examiner has not shown that it would be a serious burden to search and examine the claims of Groups I and II together, the Examiner maintains the position that the invention of Group I and the invention of Group II are related as product and process of use. The MPEP states, "a product and process of using the product can be shown to be distinct inventions if either or both of the following can be shown: (A) the process for using the product as claimed can be practiced with another materially different

product; **or** (B) the product as claimed can be used in a materially different process" (MPEP §806.05(h)). The process for using the product as claimed in Group I *can be practiced with another materially different product* other than the product as recited in Group II. Treatment of sexual dysfunction using any one of the pharmaceutical compounds known to have efficacy in treating such a condition, such as sildenafil (VIAGRA®), vardenafil (LEVITRA®), tadalafil (CIALIS®) or alprostadil (CAVERJECT®), is well known in the art. In light of the fact that the process for using the product of Group I can be practiced with another materially different product using, for example, any one of pharmaceutical compounds recited above, the Examiner maintains that the invention of Group I is patentably distinct from the invention of Group II.

Furthermore, examination of the composition of Group I is undertaken without particular regard to the function, mechanism of action or intended use of such a composition, and is performed based upon the structural elements that define and, thus, impart patentability to, the composition. Although the Examiner notes that Applicant has discovered an underlying mechanism of action of the claimed composition, i.e., that such agents are capable of modulating the activity of IK_{Ca} channel activity, and also that they are useful in treating sexual dysfunction, such does not limit the search and examination of the composition in the prior art. Complete examination of both the composition and the method of use would be required and would not only constitute an undue burden on the Examiner by requiring the examination of multiple independent and distinct inventions, but it would also hinder quality prosecution of the present claims. Furthermore, recitations of such in the preamble are generally not accorded any patentable weight where they merely recite the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness

but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) (See also MPEP §2141.02). In accordance with the MPEP at §806.05 and 806.05(h), the Examiner has properly requested restriction between the patentably distinct product of Group I and the patentably distinct process of use of Group II.

While the Examiner has noted and appreciates Applicant's remarks as to the unreasonable cost of prosecution and maintenance of additional applications directed to individual aspects of Applicant's invention (see page 2 of Applicant's remarks), it is the Examiner's position that the present restriction requirement is proper in that it provides for and facilitates quality examination on the merits. Despite the fact that Applicant has traversed on the grounds that it would constitute an undue burden to limit examination to the elected group of claims, concurrent examination on the merits of all of the claims of the present application would prohibit quality and express prosecution of the instant application, due to the fact that the present claims are drawn to a variety of patentably distinct and independent inventions, each capable of supporting separate patents, as shown by the Examiner above and for the reasons made of record in the Office Action dated December 21, 2004 (see pages 3-10).

Therefore, for the reasons above and those made of record at pages 3-10 of the Office Action dated December 21, 2004, the restriction requirement is deemed proper and is made **FINAL**.

Claims 1-6 and 14-31 are **withdrawn** from further consideration pursuant to 37 C.F.R. 1.142(b), as being drawn to non-elected inventions, there being no allowable generic or linking claim.

The claims corresponding to the elected subject matter are 7-13 and such claims are

herein acted on the merits to the extent they read on the elected subject matter identified above.

Title of Invention

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The following title is suggested: --- METHODS FOR TREATING SEXUAL DYSFUNCTION USING A MODULATOR OF IK_{Ca} CHANNEL ACTIVITY---.

Specification Objections

Appropriate correction of the following objections is required. Due to the length of the specification, the Examiner may not have identified all possible minor errors. Applicant's cooperation is requested in correcting any errors of which Applicant may become aware in the specification.

(i) The Examiner has noted the incorporation by reference of WO-A-99/38853 (see page 4, line 26 of the disclosure), WO-A-99/09983 (see page 4, line 27 of the disclosure), and WO 84/03564 (see page 85, line 3 of the disclosure), for example. The incorporation of essential material in the specification by reference to an unpublished U.S. application, foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference, if the material is relied upon to overcome any objection, rejection, or other requirement imposed by the Office. The amendment must be accompanied by a statement executed by the applicant, or a practitioner representing the

applicant, stating that the material being inserted is the material previously incorporated by reference and that the amendment contains no new matter. See 37 C.F.R. 1.57(f). Applicant is required to amend any improper incorporation by reference of essential subject matter, as the above-cited locations may not reflect all of the places at which improper incorporation by reference occurs in the present specification.

(ii) The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code at page 74, line 6 and page 40, line 26 of the disclosure. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP §608.01.

(iii) The use of the trademark LIPITOR® (atorvastatin) has been noted in this application at page 66, line 2 of the disclosure. Each letter should be capitalized wherever the name appears and be accompanied by both the generic terminology and the appropriate symbol designating a trademark (e.g., ® or ^{TM}). Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner that might adversely affect their validity as trademarks. Applicant is required to amend any improper citation of a trademark, as the above-cited location may not reflect all of the places at which improper citation of trademarks occurs in the present specification.

(iv) The Examiner has noted the description of the drawings at pages 86-90 of the present specification. This section of the disclosure should be preceded by the following title: ---BRIEF DESCRIPTION OF THE FIGURES---. See MPEP §608.01(f).

Claim Rejection - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7-13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of sexual dysfunction, does not reasonably provide enablement for the general "treatment" of a subject as is encompassed in claims 7-13 by the recitation of "...method of treatment..." without further limiting the particular condition which is to be treated. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with this claim.

In this regard, the application disclosure and claims have been compared per the factors indicated in the decision *In re Wands*, 8 USPQ2d 1400 (Fed. Cir., 1988). The factors include:

1) the nature of the invention;
2) the breadth of the claims;
3) the predictability or unpredictability of the art;
4) the amount of direction or guidance presented;
5) the presence or absence of working examples;
6) the quantity of experimentation necessary;
7) the state of the prior art; and,
8) the relative skill of those skilled in the art.

The relevant factors are addressed below on the basis of comparison of the disclosure, the claims and the state of the prior art in the assessment of undue experimentation. The breadth of the claims has also been considered and is discussed below.

The present claims are directed towards a method of treatment, comprising administering to a subject an agent capable of modulating an IK_{Ca} channel activity in the sexual genitalia of

said subject, wherein said agent is optionally admixed with a pharmaceutically acceptable carrier, diluent or excipient. The present claims are broad in that they fail to limit the presently claimed subject matter to a specific disease, disorder or condition that Applicant is intending to treat. Absent this further limitation or any factual evidence to the contrary, claims 7-13 encompass the treatment of any disease, disorder or condition in general. While the Examiner has considered the present claims in light of the accompanying specification, it is noted that the present disclosure is lacking sufficient enablement to support or to be commensurate in scope with the claimed subject matter.

The present specification is evaluated by the Examiner as directed by the Court in *In re Marzocchi et al.*, 169 USPQ 367 (CCPA 1971):

"Specification disclosure which contains teaching of manner and process of making and using the invention in terms corresponding to the scope to those used in describing and defining subject matter sought to be patented must be taken as in compliance with enabling requirement of first paragraph of 35 U.S.C. 112 *unless there is reason to doubt the objective truth of statements contain therein which must be relied on for enabling support*; assuming that sufficient reason for such doubt exists, a rejection for failure to teach how to make and/or use will be proper on that basis, such a rejection can be overcome by suitable proofs indicating that teaching contained in specification is truly enabling." (emphasis added).

The objective truth that the method as recited in present claim 7 may be used to treat a subject in general is doubted because the claim encompasses the treatment of *any and all* medical conditions, including any and all disease states, and such reads on the claimed active agent acting as a panacea.

While the Examiner cannot locate a reference teaching expressly that a panacea does not exist, the following references are relied upon in support of the Examiner's position: Kumar (cited by the Examiner, reference "U" on the attached form PTO-892) teaches, "The role of melatonin in organisms physiology has now been widely recognized, and the wealth of

information accumulated in the past two decades indicate it to be the best hormone candidate to be investigated for a universal panacea." (penultimate and last line of the abstract); Oka et al. (cited by the Examiner, reference "V" on the attached form PTO-892) teaches "At the present time, however, there is no single panacea. To achieve the maximum preventive and therapeutic effects with the minimum toxicity, two or more immunosuppressive drugs are used appropriately in combination, taking the mechanisms of action of each into consideration (penultimate and last line of the abstract); Smith et al. (cited by the Examiner, reference "W" on the attached form PTO-892) teaches "[hormone replacement therapy] is not a panacea for an unhealthy lifestyle." (line 11 of the abstract); and Rickels et al. (cited by the Examiner, reference "X" on the attached form PTO-892) teaches "Anxiolytics are not a panacea, but only tools to allow the patient to help himself or herself." (lines 11-12 of the abstract).

The art is currently unaware of any compound or combination of compounds that may be used to treat any and all diseases in a host and lacking such knowledge, the skilled artisan would be faced with the impermissible burden of undue experimentation in attempting to practice the present invention in a manner commensurate in scope with present claim 7.

Thus, for the above reasons, claims 7-13 are deemed properly rejected.

Legal Standard for Anticipation/Inherency Under - 35 USC § 102

To anticipate a claim under 35 U.S.C. 102, a single prior art reference must place the invention in the public's possession by disclosing each and every element of the claimed invention in a manner sufficient to enable one skilled in the art to practice the invention. *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565, 1576, 18 U.S.P.Q.2d 1001,

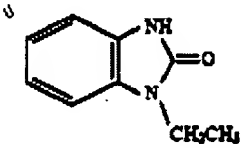
1001 (Fed. Cir. 1991); *In re Donahue*, 766 F.2d 531, 533, 226 U.S.P.Q. 619, 621 (Fed. Cir. 1985). In order to anticipate, the prior art must either expressly or inherently disclose every limitation of the claimed invention. *MEHL/Biophile Int'l Corp. v. Milgraum*, 192 F.3d 1362, 1365, 52 U.S.P.Q.2d 1303, 1303 (Fed. Cir. 1999) (citing to *In re Schreiber*, 128 F.3d 1473, 1477, 44 U.S.P.Q.1429, 1431 (Fed. Cir. 1997)); *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 U.S.P.Q.2d 1943, 1946 (Fed. Cir. 1999). In order to inherently anticipate, the prior art must necessarily function in accordance with, or include, the claimed limitations. *MEHL/Biophile,* 192 F.3d at 1365, 52 U.S.P.Q.2d at 1303. However, it is not required that those of ordinary skill in the art recognize the inherent characteristics or the function of the prior art. *Id.* Specifically, discovery of the mechanism underlying a known process does not make it patentable.

Claim Rejection - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 7 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Foulkes et al. (U.S. Patent No. 5,665,543; 1997).

Foulkes et al. teaches the use of the compound 

in a method of increasing the growth of a human being, comprising administering to the human being an

amount of the above-cited compound effective to enhance expression of human growth hormone by, and thus, growth of, the human being (col.5, lines 15-43).

Although Foulkes et al. does not expressly refer to the above-cited compound by its chemical name, Applicant's specification at page 29, lines 5-10 has been relied upon to show that the above-cited compound is synonymous with Applicant's preferred compound, also known as 1-ethyl-2-benzimidazolinone (see Applicant's disclosure at page 29, line 1). In concurrence with MPEP §2131.01, it is proper to rely on another reference for a rejection under 35 U.S.C. 102, provided that the additional reference is relied upon in order to explain the meaning of a term used in the primary reference.

The Examiner has noted that the recitation of "a method of treatment" in present claim 7 without expressly identifying the therapeutic indication that is intended by this claim does not further limit the claim to a particular therapeutic use. Thus, the claim reads on the administration of any agent capable of modulating the activity of an IK_{Ca} channel used for any therapeutic purpose. Thus, the claims are properly rejected under 35 U.S.C. 102(b).

Further Rejection of Claims 7-8 Based on Inherency

It is recognized that the prior art teachings of Foulkes et al. do not expressly recite that the above-cited compound (synonymous with "1-ethyl-2-benzimidazolinone", see preceding discussion) is capable of modulating an IK_{Ca} channel activity in the sexual genitalia of a subject, specifically, that it is capable of mediating a relaxation in the corpus cavernosal smooth muscle tone, as recited in present claims 7 and 8. The reference does, however, teach a method of increasing the growth of a human being, comprising administering to the human being an

amount of the above-cited compound effective to enhance expression of human growth hormone by, and thus, growth of, the human being (col.5, lines 15-43 of Foulkes et al.). Because the particular method steps and compounds that are present in the instant claims are also in the patent, it is deemed that the modulation of an IK_{Ca} channel activity in the sexual genitalia of a subject, specifically, that it mediates a relaxation in the corpus cavernosal smooth muscle tone, would have been inherent in the method disclosed by the prior art of Foulkes et al., whether recognized by the patentee or not. It is of particular note that Applicant has disclosed that the compound employed in the method disclosed by Foulkes et al. (i.e., 1-ethyl-2-benzimidazolinone) is known to have a modulating effect on IK_{Ca} channel activity (see Applicant's disclosure at pages 23-29, particularly p.29). However, the claiming of a new use, new function or **unknown property** that is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 U.S.P.Q. 430, 433 (CCPA 1977). See also MPEP §2112. It is irrelevant that the prior art observer did not recognize the property or function of the disputed claims; if the prior art inherently possesses that characteristic, it anticipates. Applicant's attention is further drawn to the MPEP at §2113, which states, "As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith." *In re Brown*, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972). Thus, claims 7 and 8 are properly rejected as being inherent and anticipated by Foulkes et al.

Claim Rejection - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 7-13 are rejected under 35 U.S.C. 103(a) as being obvious over Simonsen et al. ("Nitric Oxide in Deep Penile Arteries", *British Journal of Pharmacology*; 1995) in view of Pedersen et al. ("Activation of the Human Intermediate-Conductance Ca2+-Activated K+ Channel by 1-ethyl-2-benzimidazolinone is Strongly Ca2+-Dependent", *Biochimica et Biophysica Acta*; 1999), Stedman's Medical Dictionary (Twenty-Second Edition, 1973; p.623), Foulkes et al. (U.S. Patent No. 5,655,543; 1997) and Fritz et al. (U.S. Patent No. 5,792,763; 1998).

Simonsen et al. teaches the involvement of nitric oxide or a nitric oxide-related compound as the main inhibitory neurotransmitter causing vasodilatation in the tissue of horse deep penile arteries and the activation of guanylate cyclase. The accumulation of cyclic GMP

increases the open probability of the calcium-activated potassium channels, which thereby causes hyperpolarization of such channels and results in relaxation of the deep intracavernous penile arteries (isolated from the corpus cavernosum of young horses; see abstract, for example, p.2582).

Simonsen et al. further discloses that, "Thus, one might speculate whether in some cases, application of agonists that open Ca^{2+} activated K^{+}-channels would provide a more physiological treatment for impotence" (see Discussion, p.2589). The Examiner has noted that while this is a speculative statement and does not constitute a conclusory statement that such compounds are unquestionably effective in the treatment of impotence, such is not the standard by which obviousness is measured. Applicant's attention is drawn to the MPEP at §2144.08(II)(A)(4)(e), which states that, "However, obviousness does not require absolute predictability, only a reasonable expectation of success." Because such a statement by Simonsen et al. clearly intimates efficacy in treating impotence with such compounds, the Examiner considers this to constitute a reasonable expectation of success as required by the MPEP.

The differences between the Simonsen et al. reference and the presently claimed subject matter lie in that the reference does not teach:

(i) the use of a particular agonist fitting Applicant's disclosure at pages 23-29 of the present specification;

(ii) impotence as a type of erectile dysfunction;

(iii) the use such therapy in a human subject; and

(iv) the use of a pharmaceutically acceptable carrier, diluent or excipient.

However, the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains because:

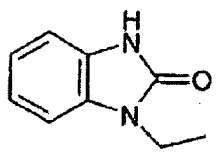
(i) Although Simonsen et al. is silent as to a particular type of calcium-activated potassium channel agonist that may be employed in a method of treating impotence, the compound 1-ethyl-2-benzimidazolinone was known in the art at the time of the invention as an activator of human intermediate-conductance calcium activated potassium channels (see abstract or introduction at p.231-232, for example). In light of the teachings of Simonsen et al., who generally discloses the use of a calcium activated potassium channel agonist for the treatment of impotence, it would have been obvious to a person of ordinary skill in the art at the time of the invention to employ 1-ethyl-2-benzimidazole as the calcium activated potassium channel agonist for the treatment of impotence, since such a compound was known in the art to possess such a function and would, therefore, be reasonably expected to exert such a therapeutic effect according to the teachings of Simonsen et al.

(ii) Stedman's Medical Dictionary (see Twenty Second Edition, 1973; p.623) has been relied upon to show that impotence, by its very definition, is a "lack of power, in the male, to copulate" and may involve an "inability to achieve penile erection or to achieve ejaculation, or both". Applicant has defined the term "erectile dysfunction" as the "inability of an adult male to ejaculate or to attain or hold an erection long enough for sexual intercourse" (see the present specification at page 20, lines 1-7). Thus, use of the term "impotence" is considered to be synonymous and interchangeable with the term erectile dysfunction as recited in the present

claims and as defined by Applicant. It would, therefore, have been obvious to a person of ordinary skill in the art at the time of the invention to use an agonist of calcium activated potassium channels as defined by Simonsen et al. for the treatment of erectile dysfunction since such terms are known to be synonymous based on their plain meaning as accepted in the art and also by the definition provided by Applicant.

(iii) Although Simonsen et al. expressly teaches the relationship of calcium activated potassium channel agonists in the relaxation of penile arteries in the horse, it is well recognized in the art that animal models, such as horses, serve to mimic the activity of pharmaceutical compounds in humans and are frequently used to test the effects of proposed compounds prior to testing or use in man. Although Simonsen et al. discloses that agonists of calcium activated potassium channels are capable of treating impotence due to their relaxing effect on penile arteries in the horse but does not expressly teach the use of a calcium activated potassium channel agonist for impotence in humans, it would have been well within the purview of the skilled artisan to use the disclosure of Simonsen et al., which suggests the use of a calcium activated potassium channel agonist in treating impotence, to adapt this therapy for use in an impotent human.

Furthermore, the art recognizes particular calcium activated potassium channel activators as pharmaceutically acceptable for administration to humans. For example, Applicant's preferred compound (see page 29 of the present specification), 1-ethyl-2-benzimidazolinone, or



, is known in the art to be useful in the treatment of human being to enhance

the expression of growth hormone and, thus, increase growth of a human being (see Foulkes et al., U.S. Patent No. 5,665,543, 1997; col.5, lines 15-53). Such serves as further support that one skilled in the art at the time of the invention would be motivated to use such calcium activated potassium channel agonists for the treatment of impotence in humans because such compounds were known to be pharmaceutically acceptable and tolerable to human subjects.

(iv) Although Simonsen et al. is silent as to the use of a pharmaceutically acceptable carrier, diluent or excipient, use of such was well known in the art at the time of the invention in the formulation of pharmaceutical compositions for administration to mammalian subjects, especially humans. Fritz et al. (U.S. Patent No. 5,792,763, 1998; col.2, lines 35-39 and 43-61) teaches a pharmaceutical composition used for the treatment of erectile difficulty, also comprising a pharmaceutically acceptable carrier, diluent or excipient. It would, therefore, have been obvious to employ a pharmaceutically acceptable carrier, diluent or excipient in the pharmaceutical composition comprising the calcium activated potassium channel agonist for the treatment of impotence as taught by Simonsen et al. Such a person would be motivated to do so in order to enhance the stability, tolerability and concentration of the active agent in the pharmaceutical formulation.

Double Patenting

Obviousness-Type

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686

F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 7-13 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 34 of copending U.S. Patent Application No. 10/017,273. Although the conflicting claims are not identical, they are not patentably distinct from each other because the differences between the presently claimed subject matter and the subject matter of the copending claims are the following:

(i) the present claims are silent as to the use of an neuropeptide Y inhibitor (NPYi);

(ii) the present claims recite that the modulation of IK_{Ca} channel activity is capable of mediating a relaxation in corpus cavernosal smooth muscle tone (see present claim 8), while the copending claim is silent as to this effect; and

(iii) the present claims recite the use of a pharmaceutically acceptable carrier, diluent or excipient.

However, to the skilled artisan, the subject matter would have been obvious because:

(i) the present claims use the word "comprising", which is considered open transitional claim language and allows for the administration of other active components in the method recited in the present claims (see MPEP §2111.03 [R-2] for a discussion of transitional phrases);

(ii) the IK_{Ca} channel modulating agent is present in both the instant claims and the

copending claims. Thus, any effect associated with such an agent, regardless of whether it is recited, is inherently present in the copending claim; and

(iii) use of such a pharmaceutically acceptable carrier, diluent or excipient was well known in the art at the time of the invention, particularly in compositions used for the treatment of erectile difficulty (see Fritz et al., U.S. Patent No. 5,792,763, 1998; col.2, lines 35-39 and 43-61) and, thus, employing such a component(s) would have been obvious to a person of ordinary skill in the art.

Claims 7-13 of the present application are not considered to be patentably distinct from copending claim 34 of U.S. Patent Application No. 10/017,273 and are provisionally rejected under obviousness-type double patenting. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Rejection of claims 7-13 is deemed proper.

No claims of the present application are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (8:30 AM-6:00 PM), alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571)-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-272-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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April 14, 2005

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